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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,819	10/11/2005	Pierre Monsan	0508-1129	4568

466 7590 07/11/2008

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1623	

MAIL DATE	DELIVERY MODE
07/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,819	MONSAN ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *63* is/are allowed.

6)☒ Claim(s) *43-52,54,55 and 57-62* is/are rejected.

7)☐ Claim(s) *53 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 03/19/08.

The amendment filed 03/19/08 affects the application, 10/527,819 as follows:

1. Claims 22-42 have been canceled. New Claims 43-63 have been added. Applicant's amendments have overcome the rejections made under 35 U.S.C. 112, first paragraph, the 102 rejections made over Miyake et al. and Letellier et al., respectively and 103 rejections made over Hiji. Consequently, these rejections are withdrawn. However, the rejections made over Roberfroid et al. is maintained. Also, a new ground(s) rejection necessitated by applicant's amendments is made herein.
2. The responsive to applicants' arguments is contained herein below.

Claims 43-63 are pending in the application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 recites the limitation wherein the GOS are present". However, there is insufficient antecedent basis for this limitation in the claim. More specifically, there is no previous reference in the claim to the term " GOS" or in the claim 43 on which claim 49 depends.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51-52, 54-55, 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirao et al. (US 4,001,435).

In claim 51, applicant claims a food composition, nutritional additive, functional food or nutraceutical for the nourishment of subject having hyperglycemic syndrome and/or type II diabetes in a subject, comprising one or more prebiotics wherein said prebiotics are chosen from the compositions of non-digestible oligosaccharides comprising chain formations of identical or different monosaccharides, whose degree of polymerization varies between 2 and 10, and whose monosaccharides are selected from the group consisting of glucose, fructose, galactose, xylose, mannose, rhamnose and fucose, and wherein a food composition substantially comprising a mixture of isomaltotriose, isomaltotetraose and isomaltopentose is excluded, and wherein fructooligosaccharides are excluded. Hirao et al. disclose applicant's food composition comprising maltose a maltooligosaccharide type of general formula [O-α-D-glucopyranosyl-(l→4)]n wherein n is an integer 2 (see abstract and example 2 and other examples, col. 4, lines 13- col. 12 line 50). Claim 52 which is drawn to the food composition wherein the prebiotics are specific oligosaccharides including maltooligosaccharide type of general formula [O-α-D-glucopyranosyl-(l→4)]n wherein n is an integer 2-10, is anticipated by Hirao et al.'s since Hirao et al.'s food composition also contains the same maltooligosaccharide type of general formula [O-α-D-glucopyranosyl-(l→4)]n wherein n is an integer 2 (i.e., maltose) (see abstract and

example 2 and other examples, col. 4, lines 13- col. 12 line 50). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for the nourishment of subjects, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim 54 is drawn to a pharmaceutical composition comprising a pharmaceutically acceptable vehicle, one or more prebiotics chosen from the compositions of non-digestible oligosaccharides comprising chain formations of identical or different monosaccharides, whose degree of polymerization varies between 2 and 10, and whose monosaccharides are chosen from glucose, fructose, galactose, xylose, mannose, rhamnose and fucose, and wherein fructooligosaccharides are excluded. Hirao et al. disclose applicant's composition comprising maltose a maltooligosaccharide type of general formula [O-α-D-glucopyranosyl-(l→4)]n wherein n is an integer 2 (see abstract and example 2 and other examples, col. 4, lines 13- col. 12 line 50). Claim 55, 57-58 which are drawn said pharmaceutical composition according to claim 54 wherein the prebiotics are specific oligosaccharides including maltooligosaccharide type of general formula [O-α-D-glucopyranosyl-(l→4)]n wherein n is an integer 2-10 and wherein the composition can be orally administered and wherein the composition is administered at specific g/day, are anticipated by Hirao et al.'s since Hirao et al.'s composition also contains the same maltooligosaccharide type of general formula [O-α-D-glucopyranosyl-(l→4)]n wherein n is an integer 2 (i.e., maltose), and can be orally administered (see abstract and example 2 and other examples, col. 4, lines 13- col. 12 line 50). It should be noted that claim 58 are composition claims and the administration rate of the composition does not further limit the claims It should be noted that it is well settled that "intended use" of a composition or product, e.g., for the

nourishment of subjects, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claims 51-52, 54-55, 57-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Carobbi et al. (US 4,978,397).

In claim 51, applicant claims a food composition, nutritional additive, functional food or nutraceutical for the nourishment of subject having hyperglycemic syndrome and/or type II diabetes in a subject, comprising one or more prebiotics wherein said prebiotics are chosen from the compositions of non-digestible oligosaccharides comprising chain formations of identical or different monosaccharides, whose degree of polymerization varies between 2 and 10, and whose monosaccharides are selected from the group consisting of glucose, fructose, galactose, xylose, mannose, rhamnose and fucose, and wherein a food composition substantially comprising a mixture of isomaltotriose, isomaltotetraose and isomaltopentose is excluded, and wherein fructooligosaccharides are excluded. Carobbi et al. disclose applicant's food composition comprising lactulose of formula O-β-D-galactopyranosyl-(l→4)-O-β-D-fructofuranose (see abstract and example 1, col. 3 line 35 to col. 4, line 13; also see other examples). Claim 52 which is drawn to the food composition wherein the prebiotics are specific oligosaccharides including lactulose of formula O-β-D-galactopyranosyl-(l→4)-O-β-D-fructofuranose, is anticipated by Carobbi et al.'s since Carobbi et al.'s food composition also contains the same lactulose of formula O-β-D-galactopyranosyl-(l→4)-O-β-D-fructofuranose (see abstract and example 1, col. 3 line 35 to col. 4, line 13; also see other examples). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for the nourishment of subjects, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2

USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claims 59-62 which are drawn said food composition according to claim 51 wherein the prebiotics are specific oligosaccharides including lactulose of formula O-β-D-galactopyranosyl-(l→4)-O-β-D-fructofuranose and wherein the composition can be orally administered and wherein the composition is administered at specific g/day, are anticipated by Carobbi et al. since Carobbi et al.'s composition also contains the same lactulose of formula O-β-D-galactopyranosyl-(l→4)-O-β-D-fructofuranose (see abstract and example 1, col. 3 line 35 to col. 4, line 13; also see other examples) and can be orally administered (see abstract and example 1, col. 3 line 35 to col. 4, line 13; also see other examples). It should be noted that claim 62 is a composition claim and the administration rate of the composition does not further limit the claims. It should be noted that it is well settled that "intended use" of a composition or product, e.g., for the nourishment of subjects, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim 54 is drawn to a pharmaceutical composition comprising a pharmaceutically acceptable vehicle, one or more prebiotics chosen from the compositions of non-digestible oligosaccharides comprising chain formations of identical or different monosaccharides, whose degree of polymerization varies between 2 and 10, and whose monosaccharides are chosen from glucose, fructose, galactose, xylose, mannose, rhamnose and fucose, and wherein fructooligosaccharides are excluded. Carobbi et al. disclose applicant's composition comprising lactulose of formula O-β-D-galactopyranosyl-(l→4)-O-β-D-fructofuranose (see abstract and example 1, col. 3 line 35 to col. 4, line 13; also see other examples). Claims 55, 57-58 which are drawn said pharmaceutical composition according to claim 54 wherein the prebiotics are specific

oligosaccharides including lactulose of formula O-β-D-galactopyranosyl-(1→4)-O-β-D-fructofuranose and wherein the composition can be orally administered and wherein the composition is administered at specific g/day, are anticipated by Carobbi et al. since Carobbi et al.'s composition also contains the same lactulose of formula O-β-D-galactopyranosyl-(1→4)-O-β-D-fructofuranose (see abstract and example 1, col. 3 line 35 to col. 4, line 13; also see other examples) and can be orally administered (see abstract and example 1, col. 3 line 35 to col. 4, line 13; also see other examples). It should be noted that claim 58 are composition claims and the administration rate of the composition does not further limit the claims It should be noted that it is well settled that "intended use" of a composition or product, e.g., for the nourishment of subjects, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberfroid et al. (Annual Review of Nutrition, (1998) vol. 18, pp. 117-43).

In claim 43, applicant claims A method for treating hyperglycemic syndrome and/or type II diabetes in a subject, comprising: administering to a subject in need thereof an effective

amount of prebiotic non-digestible oligosaccharides, wherein said prebiotic non-digestible oligosaccharides comprise chain formations of monosaccharides selected from the group consisting of glucose, fructose, galactose, xylose, mannose, rhamnose and fucose, and whose degree of polymerization is between 2 and 10. Claims 44-48 are drawn to the method of claim 43 wherein the subject has specific conditions and wherein specific prebiotic or oligosaccharides including fructooligosaccharide are used.

Roberfroid et al. disclose that inulin-type fructans can be used to treat non-insulin dependent diabetes (type II diabetes) and obesity (see abstract). Furthermore, Roberfroid et al. disclose the inulin-type fructans or fructooligosaccharides $G_{py}F_n$ (α-D-glucopyranosyl-[β-D-fructofuranosyl]$_{n-1}$-D-fructofuranoside) and $F_{py}F_n$ (β -D-fructopyranosyl-[β-D-fructofuranosyl]$_{n-1}$-D-fructofuranoside) (see page 119, 2nd paragraph and figure 1). Roberfroid et al. disclose that n (the number of β-D-fructofuranose units or the degree of polymerization) is from 2 to 70(see page 119, 2nd paragraph and figure 1). It should be noted that in the $G_{py}F_n$ inulin-type fructan or oligosaccharide the linkage between the O-α-D-glucopyranosyl unit and the D-fructofuranosyl unit is (1→2) and is also (1→2) between the [O-β-D-fructofuranose units (see page 119, figure 1). That is, the inulin-type fructan or oligosaccharide compound $G_{py}F_n$ can represent a compound of the general formula O-α-D-glucopyranosyl- (1→2)-[O-β-D-fructofuranosyl-(1→2)]$_n$ for example, when n = 4 (see page 119, figure 1). Also, Roberfroid et al. disclose that the $G_{py}F_n$ compounds can be used in food industry (see page 120, 1st paragraph). It should be noted that applicant's independent claim 43 (as recited) also encompasses the treatment of type II diabetes in a patient with hyperglycemic syndrome.

The difference between applicant's claimed method and the method taught by Roberfroid et al. is that Roberfroid et al. do not treat diabetes or obesity with the $G_{py}F_n$ inulin-type fructan or oligosaccharide, per se. However, Roberfroid et al. suggest that the inulin-type fructan or oligosaccharide $G_{py}F_n$ can be used to treat non-insulin dependent diabetes (type II diabetes) and obesity (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have treated diabetes or obesity in a subject with the $G_{py}F_n$ inulin-type fructan or oligosaccharide suggested by Roberfroid et al.

One having ordinary skill in the art would have been motivated to treat diabetes or obesity in a subject with the $G_{py}F_n$ inulin-type fructan or oligosaccharide suggested by Roberfroid et al., since Roberfroid et al. suggest that it can be used and based on factors such as need and/or availability. It should be noted that the use of specific dosage depends on factors such as the severity of the diabetes or obesity and the type, weight and age of the individual treated.

Allowable Subject Matter

Claims 53 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Though the composition of the present invention are similar to the compositions of the prior art, the composition of claim 53 and 56 possess differences to the composition of prior art documents and these differences are not suggested in the prior art, nor are obvious over the prior art. Furthermore, the composition of claim 63 is not suggested in the prior art, nor is obvious over the prior art.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are not found convincing.

The applicant argues that Contrary to the assertions of the Official Action, ROBERFROID et al. do not suggest that the food composition described in Fig. 1 (p. 119) could be used to treat diabetes and obesity. However, Roberfroid et al. disclose that inulin-type fructans can be used to treat non-insulin dependent diabetes (type II diabetes) and obesity (see abstract). And as set forth in the above rejection, one skilled person would have the motivation and a reasonable expectation of success to utilize the composition in a method for treating type II diabetes in a subject as recited in the claimed invention.

The applicant argues that at page 129, ROBERFROID et al. note the contradictory "effects of these fructans on glycemia and insulinemia, emphasizing "that these effect may depend on physiological (fasting versus postprandial state) or disease (diabetes) conditions." In this regard, ROBERFROID et al. also state, "the glycemic response during a glucosetolerance test after overnight fasting is identical in control and OFr-fed rats". However, Roberfroid et al. disclose that inulin-type fructans can be used to treat non-insulin dependent diabetes (type II diabetes) and obesity (see abstract). And as set forth in the above rejection, one skilled person would have the motivation and a reasonable expectation of success to utilize the composition in a method for treating type II diabetes in a subject as recited in the claimed invention.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

July 6, 2008.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623